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| 10/571,986 | 03/14/2006 | Joel Stephane Rossier | JYG182AUSA | 5557 |
| 270 7590 09/04/2009 HOWSON & HOWSON LLP 501 OFFICE CENTER DRIVE SUITE 210 FORT WASHINGTON, PA 19034 | | | | |
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| 1795 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary

Application No.

10/571,986

Applicant(s)

ROSSIER ET AL

Examiner

GURPREET KAUR

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 42-82 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 42-82 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/309)
Paper No(s)/Mail Date 12/06/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Objections

Applicant is advised that should claim 79 be found allowable, claim 80 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Invocation of 35 USC § 112, sixth paragraph

When claim language invokes 35 USC 112, sixth paragraph, a limit on is set on how broadly the PTO may construe means-plus-function language under the rubric of reasonable interpretation (See *Donaldson*, 16 F.3d at 1194, 29 USPQ2d at 1850). Additionally, the Federal Circuit has held that applicants before the USPTO have the opportunity and the obligation to define their inventions precisely during proceedings before the PTO (See *In re Morris*, 127 F.3d 1048, 1056–57, 44 USPQ2d 1023, 1029–30 (Fed. Cir. 1997)). A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase “means for” or “step for;”
- (B) the “means for” or “step for” must be modified by functional language; and
- (C) the phrase “means for” or “step for” must not be modified by sufficient structure, material, or acts for achieving the specified function.

Art Unit: 1795

Instant claim 1 at line 5 recites in part the limitation "means for applying pressure." Claims 46 and 47 at line 2 recites "means for imposing pressure." This limitation utilize the terms "means for"; the "means for" is modified by functional language, specifically "applying and imposing"; and the phrase "means for" is not modified by sufficient structure, material, or acts for achieving the specified function. Therefore, claims 1, 46 and 47 has invoked 35 USC 112, sixth paragraph. Regarding claims 1, 46 and 47, Applicant's specification supports means for applying pressure by gravity or external actuator (see paragraphs 13 and 14). Therefore, this limitation will be interpreted as pertaining only to the corresponding structure, material or acts described in the specification, namely gravitational force or external actuator, or equivalents thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1795

Claims 1, 2, 42-47, 49-60, 62-74 and 76-82 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Rossier et al. (WO 03/004160).

Regarding claim 1, 64 and 65, Rossier et al. teaches an electrochemical assay device with integrated amperometric flow monitoring means (integrated electrodes (see abstract and page 4, lines 16-25) comprising:

a microfluidic system (microchip¹) comprising covered (sealed) microchannel (2) having inlet and outlet (two apertures one each extremity) (see page 4, lines 1-3; figure 2B);

means for (microfluidic control unit) for applying a pressure difference between the inlet and the outlet of microfluidic system to generate a flow of solution within covered microchannel (see page 13, lines 19-27);

at least one electrode integrated (5) in a wall portion of the microchannel (see figure 1A), it is inherent the electrode has a precise size and location since it is integrated with the microchannel;

integrated electrode (5) is adapted to monitor the solution flow by amperometric measurement and is also adapted to electrochemically detect an analyte of interest during the assay (see page 4, lines 16-25 and page 5, lines 3-16).

Regarding claim 2, the solution comprises reporter molecule (electroactive species) for monitoring the solution flow at integrated electrode (5) by amperometric measurement (see page 4, lines 24-26 and page 5, lines 3-4).

Regarding claims 42 and 43, the microchip (1) can be displaced in x, y and z directions by automated means or manually (see page 4, lines 13-15, page 13, lines 1-3 and figure 3) and is placed in the solid support (holder 7) (see figure 2A). Therefore, it is inherent the manual displacement of the microchip would simultaneously tilt the solid support as well and would cause the difference in solution height between the inlet and outlet of the microchannel which would cause pressure difference induced by gravity.

Regarding claim 44, microchip system is adapted to generate a flow of solution in the sealed microchannel by potential (see page 15, lines 4-6) i.e. without pumping means.

Regarding claims 45, 46 and 47, the microchip system consist of means for (microfluidic control unit, 11) to pump the solution through the microchannel and underpressure (aspirating) the solution in the microchannel (see page 10, lines 25-30 and figure 8).

Regarding claims 49 and 51, microchip system is made of polymer, glass, quartz or a combination thereof (see page 7, lines 7-11). Glass is inherently a light-transparent material.

Regarding claim 50, microchip comprises a polymer layer laminated or glued to seal the microchip (see claim 17 and figure 2B).

Claim 52 is a product-by-process claim because the process of plasma etching, laser photoablation or embossing the substrate does not further limit the structure of the microfluidic system. In a product-by-process claim the method, i.e. plasma etching, laser photoablation or embossing, of forming the microfluidic system is not a limitation that is examined. See *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972) (see also MPEP 2113).

Regarding claim 53, microchip is comprised of network of microchannels (see page 7, lines 3-6 and claim 15).

Regarding claim 54, the microchannel is covered by sealing plate (7') fixed over the microchannel and maintained by external pressure (see page 20, lines 6-9 and figure 2B).

Regarding claim 55, the electrode is made up of conductive surface (gold) (see page 20, lines 28-29).

Regarding claims 56-58, microchannel contains antibodies, enzymes, and oligonucleotides which are inherently biological molecules and are dispensed in the microchannels (see page 15, lines 10-15 and 25-28).

Regarding claim 59, the microfluidic control unit can block the sample in the microchannel (see page 8, lines 6-9).

Regarding claim 60, Rossier et al. teaches that solution is blocked in the microchannel by the microfluidic control unit (see page 8, lines 6-12).

Regarding claim 62, the flow of solution is used for affinity sorbent (immunosorbent) assay to perform incubation in the microchannel (see page 5, lines 8-13).

Regarding claim 63, the electrode is layered with diffusion layer; hence the electrode is not in direct contact with the liquid (see page 21, lines 5-7).

Regarding claim 66, Rossier et al. teaches that steps preceding the detection, electrochemical assay is performed in order to determine the efficiency of the microfluidic control unit and conductivity measurements allow assessment of whether the microchannel is filled with solution (see col. 16, lines 21-27).

Regarding claims 67, 77 and 78, Rossier et al. teaches a method of performing an electrochemical assay in a microchip with integrated amperometric flow monitoring means (integrated electrodes) (see abstract and page 3, lines 20-23 and page 4, lines 24-25) comprising:

a microfluidic system (microchip¹) comprising covered (sealed) microchannel (2) having inlet and outlet (two apertures one each extremity) (see page 4, lines 1-3; figure 2B), at least one electrode integrated (5) in a wall portion

Art Unit: 1795

of the microchannel (see figure 1A), it is inherent the electrode has a precise size and location since it is integrated with the microchannel;

filling a sample at the inlet (microstructure tip) of the covered microchannel to fill the microchannel (see page 10, lines 24-27);

applying a pressure difference between the inlet and the outlet of microfluidic system to generate a flow of solution within covered microchannel (see page 13, lines 19-27);

integrated electrode (5) is adapted to monitor the solution flow by amperometric measurement and is also adapted to electrochemically detect an analyte of interest during the assay (see page 4, lines 16-25 and page 5, lines 3-16).

Regarding claim 68, multi-step assay is performed wherein the steps b) to d) are repeated to load samples 31-34 in the microchannel (see figure 8 and page 10, lines 22-30 over page 11, lines 1-5).

Regarding claims 69, 71 and 72, Rossier teaches that microchip (1) can be displaced in x, y and z directions by automated means or manually (see page 4, lines 13-15, page 13, lines 1-3 and figure 3) and is placed in the solid support (holder 7) (see figure 2A). Therefore, it is inherent the manual displacement of the microchip simultaneously would tilt the solid support as well and would cause the difference in solution height between the inlet and outlet of the microchannel which would cause pressure difference induced by acceleration.

Regarding claim 70, microchip system is adapted to generate a flow of solution in the sealed microchannel by potential (see page 15, lines 4-6) i.e. without pumping means.

Regarding claim 73, Rossier et al. teaches that electrochemical assay of analyte occurs upon blocking the solution in the microchannel (see page 11, lines 3-5).

Regarding claim 74, Rossier et al. teaches that solution is blocked in the microchannel by the microfluidic control unit (see page 8, lines 6-12).

Regarding claim 76, Rossier et al. teaches electrochemical signals can be used to determine the accuracy of the solution flow controlled by the microfluidics control unit (see page 11, lines 11-17 and figure 10).

Regarding claims 79 and 80, Rossier et al. teaches that steps preceding the detection, electrochemical assay is performed in order to determine the efficiency of the microfluidic control unit and conductivity measurements allow assessment of whether the microchannel is filled with solution (see col. 16, lines 21-27).

Regarding claims 81 and 82, Rossier et al. teaches the steps of performing immunoassays with electrochemical detection (see page 16, lines 9-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48, 61, 64 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossier et al. (WO 03/004160).

Regarding claim 48, Rossier et al. teaches the reporter molecule (electroactive species) is ferrocene methanol (see page 11, lines 14-16 and page 20, lines 28-30 and over to page 21, line 1).

Rossier et al. does not explicitly teach ferrocene is the reporter molecule.

However, it is well known in the art a ferrocene methanol is an analog of ferrocene.

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to use ferrocene instead of ferrocene as a reporter molecule.

Regarding claims 61 and 75, Rossier et al. teaches that solution is blocked in the microchannel by the microfluidic control unit and can also be couple to solution reservoir containing blocking agents and other solutions (see page 8, lines 6-12).

Rossier et al. does not explicitly indicate that both the inlet and outlet are blocked with immiscible liquid. However, it is well known in the art to use blocking agents in the microchannel to control flow of the liquid.

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to dispose a blocking agent such as immiscible liquid in the inlet to cause blockage in the microchannel to control the flow of the liquid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday (Alternate Friday Off), 8:00-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571)272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. K./

Examiner, Art Unit 1795

/Brian J. Sines/

Supervisory Patent Examiner, Art Unit 1795